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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,478	08/17/2001	Titus Kaletta	D0590/7019	4784
23628	7590	02/12/2004	EXAMINER KAUSHAL, SUMESH	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			ART UNIT 1636	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/857,478

Applicant(s)

KALETTA ET AL.

Examiner

Sumesh Kaushal Ph.D.

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 116-133 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 116-133 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

*Applicant's response filed on 11/19/03 has been acknowledged.*

*Claims 1-115 are canceled.*

*Claims 116-133 are newly filed.*

*Claims 116-133 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121 (<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**.*

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.*

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 117-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 117 and 118 are indefinite because it is unclear what is the criterion that defines "the strict standard protocol of measurement". Strictness is a relative term wherein the metes and bounds cannot be ascertained. In addition it is unclear whose standard protocol would be used in this context and how "standard" it have to be.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 116-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb et al (Genetics 137: 107-120, 1994, ref of record) in view of Martinelli et al (Semin. Cell Dev Biol. (5):459-67, 1997).

The instant claims are drawn to a method for testing the influence of a compound on *C. elegans*, comprising exposing the nematode to the compound and generating a phenotypic profile for the nematode upon exposure to the compound by measuring and scoring a plurality of changed characteristics and comparing the phenotypic profile a library of reference phenotypic, wherein the reference phenotypic profiles is stored electronically on a database.

Gottlieb et al teaches a method of making *C. elegans* libraries based upon phenotypic profiles of the worm (abstract). Regarding claims 121, 126-127 and 129 the cited art teaches screening of phenotypic profiles in daf-mutant *C. elegans* by measuring changes in identifiable characteristic of the worm as compared to worm without the daf-mutations (page 108, col.2, para.2; page 112, table 2). Regarding claims 116-120 and 130-133 the cited art further teaches subsequent screening of phenotypic profiles of worms each of which has different defects (page 114, table-3, page 116, table-4, page 117, table-5). The cited art further teaches screening of *C. elegans* libraries by exposing the variety of mutant worms to a chemical compound e.g. SDS (page 115, fig-3). The cited art further teaches screening of *C. elegans* libraries by exposing the variety of mutant worms to different environmental changes e.g. pheromone concentration, food availability and temperature (page 118, fig-4, page 111,

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table-1, page 112, table-2, page 114, table-3). In addition regarding claims 122-125 the cited art teaches characterization of phenotypic profiles based upon dauer formation, dauer bypass, pharynx remodeling, pharyngeal pumping, intestine cell color, molting cycle, body growth, body shapes, presence of ciliated sensory neurons, temperature sensitivity, gonad development, laying dead or live eggs and longevity.

However the cited art does not teach comparing the generated phenotypic profiles with reference phenotypic profiles stored electronically on a database.

Martinelli teaches a gene expression and development database for *C. elegans*. The cited art teaches that the expression data from in-situ hybridization, immunolocalization and reporter constructs have been put into the ACeDB database, which is used to store and disseminate most types of *C. elegans* data. In the database, the gene-expression patterns are linked to genes, sequences, cells, organs and the developmental stage in which expression occurs. The cited art further teaches that such an approach can be used to compare phenotypic profiles. For example, an accessory program named 'Angler' can be used to browse sectional Nomarski-images of the worm embryo during early development, and to relate these images to overlaid cell lineage data and 3-D schematic views of cell positions (see abstract).

Thus it would have been obvious to one ordinary skill in the art at the time of filing to modify the method of Gottlieb who teaches a method for screening compounds and *C. elegans* libraries based upon phenotypic profiles by incorporating the phenotypic information into an electronic database as taught by Martinelli. One would have been motivated to do so because electronic data bases provides easy access to the stored information. One would have a reasonable expectation of success, since ACeDB database was readily available at the time of filing. Thus the invention as claimed is *prima facie* obvious in view of cited prior art of record.

### **Conclusion**

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on 571-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*S. Kaushal*  
Patent examiner

*Gerry Leffers*  
**GERRY LEFFERS**  
**PRIMARY EXAMINER**